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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,223	01/24/2001	Raoul E. Benveniste	015280196310	2782

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/769,223

Applicant(s)

BENVENISTE, R. E., ET AL.

Examin r

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this c mmunication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

Restriction Requirement

35 U.S.C. § 121

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 1-3, 12, 13, 15, 16, drawn to a **method of immunizing** a human against HIV infection employing an **attenuated HIV** carrying a **nef-deletion**, classified in class 435, subclass 236, and class 424, subclasses 188.1 and 208.1.
- b. Group II, claim(s) 1, 4-6, 12, 15, 16, drawn to a **method of immunizing** a human against HIV infection employing an HIV **Env subunit immunogen**, classified in class 424, subclasses 188.1 and 208.1, and class 530, subclass 350.
- c. Group III, claim(s) 1, 7-9, 12, 15, 16, drawn to a **method of immunizing** a human against HIV infection employing an attenuated HIV carrying a **gag-deletion**, classified in class 435, subclass 236.
- d. Group IV, claim(s) 1, 7, 10, 12, 15, 16, drawn to a **method of immunizing** a human against HIV infection employing a **betapropiolactone inactivated virus**, classified in class 435, subclass 238.
- e. Group V, claim(s) 1, 11, 12, 14-16, drawn to a **method of immunizing** a human against HIV infection employing an **infectious form** of HIV, classified in class 424, subclasses 188.1 and 208.1.
- f. Group VI, claim(s) 17, 18, and 20, drawn to a **method of vaccinating** a human against HIV infection using an immunogen that will **induce a cell-mediated immune response without inducing a humoral immune response**, classified in class 424, subclass 188.1 and 208.1.
- g. Group VII, claim(s) 18 and 19, drawn to a **method of vaccinating** against a mammalian retrovirus using an **SIV** immunogen, classified in class 424, subclasses 188.1 and 208.1.
- h. Group VIII, claim(s) 18 and 21, drawn to a **method of vaccinating** against a mammalian retrovirus using an **HTLV-I** immunogen, classified in class 424, subclass 207.1.
- i. Group IX, claim(s) 18 and 22, drawn to a **method of vaccinating** against a mammalian retrovirus using an **HTLV-II** immunogen, classified in class 424, subclass 207.1.
- j. Group X, claim(s) 18 and 23, drawn to a **method of vaccinating** against a mammalian retrovirus using an **foamy virus** immunogen, classified in class 424, subclass 207.1.

k. Group XI, claim(s) 24, drawn to a **vaccine** comprising an immunogen capable of **protecting a human against HIV infection**, classified in class 424, subclass 208.1.

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l. Group XII, claim(s) 25, drawn to a **vaccine** comprising an immunogen that is **capable of eliciting a cell-mediated immune response**, classified in class 424, subclass 184.1.

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Applicants are advised that claims 18-23 are vague and indefinite. The claims are directed toward a method of vaccinating a human against any mammalian retroviral infection by administering an immunogen obtained from various non-human (i.e., SIV) and human viral sources (i.e., HTLV-I, HTLV-II, foamy virus). The claim language is confusing since humans are not normally infected by SIV. Are the claims directed toward the administration of an SIV immunogen to a human to protect against an HIV infection? Alternatively, are the claims directed toward the administration of an SIV immunogen to protect a non-human primate against SIV infection? For the purpose of the restriction analysis, the Examiner has assumed that the claims are drawn toward the protection of a human against a human retroviral infection through the administration of various immunogens derived from both non-human (e.g., SIV, feline foamy virus) and human sources (e.g., HTLV-I, HTLV-II, human foamy virus). Applicants are required to amend the claim language in the next reply to address this concern.

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2. The inventions are distinct, each from the other because of the following reasons:

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3. Inventions I-XII are all are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified methodologies employs structurally and functionally different immunogens (e.g.,

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attenuated viruses, inactivated viruses, live viruses, subunit immunogens). Moreover, each of the identified vaccine compositions is directed toward a structurally and functionally different product. Finally, none of the products identified are required by any of the methodologies. Thus, each group identified is clearly drawn toward a different inventive concept.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

Correspondence

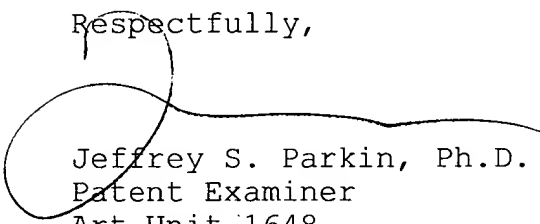
7. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648**.

8. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be

5 directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

10 9. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. a message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

15 Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

24 July, 2002